

CETILAR® PATCH AND CETILAR® TAPE CERTIFIED CLASS 2A MEDICAL DEVICES.

CE certification as Class 2A Medical Devices granted by the Higher Institute for Health officially clears the way for new commercial growth for the Cetilar® range products. The American FDA awards the Cetylated Esters patented by PharmaNutra GRAS substance recognition.

Pisa, 22nd December 2020 - [PharmaNutra S.p.A.](#) (the “Company”), specialised in iron-based nutritional supplements and in medical devices for muscles and joints, communicates that it has obtained two important certifications by the Notified Body of the Higher Institute for Health (ISS) and the U.S. Food and Drug Administration (FDA).

The Company has received CE certification from the ISS classifying the products Cetilar® Patch and Cetilar® Tape as Class 2A Medical Devices. With Cetilar® Cream - already certified Class 2A - they now form a line of Cetylated Ester-based (CFA) medical devices for the well-being of muscles and joints.

Certification of Cetilar® Patch and Cetilar® Tape as Class 2A Medical Devices is not only a further qualitative confirmation of the Cetilar® line products. It is also a fundamental distribution step forward, for both the Italian and the international markets, as it enables the Company to commercialise at European level without needing any further certifications issued by single country authorities, and to obtain the free sale certificate required by non-EU Countries.

The Company also communicates that it has obtained GRAS (acronym for *Generally Recognized As Safe*) acknowledgement for its patented Cetylated Esters (CFA). As is required by the FDA, that acknowledgement was obtained through the admissibility procedure by a panel of qualified experts, based on scientific data related to the safety of CFA. GRAS certification will enable PharmaNutra to trade new CFA- based oral formulas in the United States, thus considerably expand its market for Cetilar® products, developed for topical use until now.

Germano Tarantino, Scientific Director of PharmaNutra S.p.A. comments: *“We are really satisfied with having received these important acknowledgements for our muscle and joint product line. Firstly, because the processes were complex and kept our Regulatory and Quality Assurance department busy for a long time: Obtaining these new certifications is an important goal. Recognising the products as Class 2A Medical Devices will enable the Cetilar® brand to grow from a commercial point of view, in Italy and abroad, where the*

distribution process has only just started and growth margins are exceedingly broad. Then GRAS status recognition also fits into this context, for the commercialisation of any new oral Cetylated Ester-based products: a true turning point for developing new patented formulas and CFA-based products”.

PharmaNutra S.p.A.

Founded and led by the President Andrea Lacorte and Vice President Roberto Lacorte, PharmaNutra was established in 2003. It develops unique nutritional supplements and innovative medical devices, handling the entire production process, from proprietary raw materials to the finished product. The effectiveness of its products is documented by considerable scientific proof. The Group distributes and sells its products in Italy and abroad. In Italy, products are sold through a network of approximately 130 Pharmaceutical Representatives serving doctors and also exclusively selling PharmaNutra products to pharmacies throughout Italy. Products are sold in 50 countries abroad, through 32 partners selected from among the finest pharmaceutical companies. Over the years, PharmaNutra has stood out in the production of iron-based nutritional supplements with the trademark SiderAL[®], where it can claim important Sucrosomial Technology[®] patents. The Group has developed a precise strategy for the management and production of intellectual property, founded on the integrated management of all the various elements: proprietary raw materials, patents, brands and clinical evidence.

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